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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,298	12/10/1999	JOHN FIKES	18623-014600	8697

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/458,298	FIKES ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-63* is/are pending in the application.

4a) Of the above claim(s) *43-45,47-49,51-55,58,60,63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,42,46,50,56,57,59,61 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of Group 11 and the peptide KVAELVHFL in the paper filed 12/3/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

2. Claims 43,47,48 are withdrawn from further consideration pursuant to 37 CFR 1 .142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in paper filed 12/3/2003.

3. Applicant's election of the species 9mer and fused to a linker in the paper filed 6/3/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

4. Claims 44,45,49,51-55,58,60,63 are withdrawn from further consideration pursuant to 37 CFR 1 .142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in paper filed 6/3/204.

5. Claims 41,42,46,50,56,57,59,61,62 are under consideration.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 41,42,46,50,56,57,59,61,62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,602,510. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, both sets of claims encompass the peptide KVAELVHFL and a composition containing said peptide attached to a linker (see claim 6 of US Patent 6,602,510).. The composition of claim 2 of 6,602,510 would also contain tissue culture media or PBS which is a pharmaceutically acceptable carrier. The composition of claim 1 of US Patent 6,602,510 contains KVAELVHFL and other peptides.

8. Claims 41,42,46,50,56,57,59,61,62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31,35-39 of copending Application No. 10/149915. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, both sets of claims encompass the peptide KVAELVHFL and a composition containing said peptide attached to a linker (see claim 6). The composition of claim 17 would also contain tissue culture media or PBS which is a pharmaceutically acceptable carrier. The composition of claims 2-5,18-26 contains KVAELVHFL and other peptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Applicant needs to update the status of all US applications disclosed in the specification.

10. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it discloses priority claims to applications to which priority is no longer claimed in the instant application.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 41,42,46,50,56,57,59,61,62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent 5,342,774) in view of Rotzschke et al. and Rammensee et al. (WO 92/21033) as evidenced by Rammensee et al. (US Patent 5,747,269).

The Rammensee et al. (US Patent 5,747,269) reference is a 371 of WO 92/21033 and thus contains a certified English language translation of WO 92/21033 (German language publication). Thus, the Rammensee et al. (US Patent 5,747,269) patent is cited only in the context of providing a translation of WO 92/21033. Passages cited in the instant rejection will refer to the English language version of WO 92/21033 (US Patent 5,747,269), wherein said passages are found in WO 92/21033.

Boon et al. teach MAGE 3, wherein the peptide KVAELVHFL is found in said protein (see Examples 23, 25, column 24, fourth paragraph). Boon et al. teach a nucleic acid encoding MAGE-3 with the appropriate delineated coding sequence (see Figure 20). The MAGE-3 amino acid sequence (derived from the aforementioned nucleic acid using the art known genetic code) contains peptide KVAELVHFL. Boon et al. teach

that MAGE-3 is a TRAP which encodes TRA (tumor rejection antigen) wherein it is desireable to elucidate the identity of the actual peptide recognized by the CTL (see columns 23-26 and columns 3-4). Boon et al. do not teach the peptide KVAELVHFL. Rammensee et al. disclose that using a motif screening system that the identity of a tumor cell peptide reactive with CTL can be determined (see column 4 and abstract). Rammensee et al. disclose that HLA 0205 binds a 9mer peptide with an anchor residue of L at position 9. (see TABLE 5) The claimed peptide has a L amino acid at position 9. Rammensee et al. teach compositions containing mixtures of such peptides wherein said composition would contain tissue culture media which would constitute a "pharmaceutically acceptable carrier" (see column 4, first incomplete paragraph). Rammensee et al. teach said peptide attached to linker amino acids (see column 5, first complete paragraph). Rotzschke et al. disclose that the such motifs can be used to scan protein sequences to identify T cell epitopes (see page 453, first column, third paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Boon et al. teach MAGE 3, wherein the peptide KVAELVHFL is found in said protein and that MAGE-3 is a TRAP which encodes TRA (tumor rejection antigen) wherein it is desireable to elucidate the identity of the actual peptide recognized by the CTL whilst Rammensee et al. disclose that using a motif screening system that the identity of a tumor cell peptide reactive with CTL can be determined and that HLA 0205 binds a 9mer peptide with an anchor residue of L at position 9 and Rotzschke et al. disclose that the such motifs can be used to scan protein sequences to identify T cell epitopes.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644